

Patent
42479-2500**IN THE CLAIMS:**

Cancel without prejudice Claims 16, 17 and 18.

1 1-8. (Cancelled)

1 9. (Currently Amended) An agglutination immunoassay method of quantifying a
2 predetermined antigen in a sample of whole blood, comprising the steps of:

3 providing a sample of the whole blood;

4 adding a hemolysis reagent and a latex reagent comprising of insoluble latex
5 carriers onto which antibodies specifically reacting with the predetermined antigen in the sample
6 of whole blood have been immobilized, directly to the sample of the whole blood without any
7 pre-treatment of the whole blood;

8 hemolysing the whole blood sample with the hemolysis reagent to hemolyse the
9 blood corpuscles;

10 ~~reacting the hemolysed whole blood sample in forming an agglutination reaction~~
11 ~~to form a reaction mixture product~~ wherein a predetermined antigen in the hemolysed whole
12 blood sample specifically reacts with ~~an antibody~~ the antibodies immobilized onto ~~an~~ the
13 ~~insoluble carrier~~ latex carriers;

14 irradiating the reaction products in the sample with radiation which ~~include~~
15 includes a wavelength within a range of 700 nm to 1000 nm which is substantially free from
16 absorption by both hemoglobin and the hemolysis reagent; and

17 measuring, only in a the wavelength range which is substantially free from
18 absorption by both hemoglobin and the hemolysis reagent, an absorbance of the incident
19 radiation through the reaction mixture to determine the quantity of antigens in the sample.

Patent
42479-2500

1 10. (Cancelled)

1 11. (Currently Amended) The immunoassay method of Claim 10, wherein the step
2 of hemolysing is performed with a saponin aqueous solution as the hemolysis reagent.

1 12. (Cancelled)

1 13. (Currently Amended) An agglutination immunoassay method of quantifying a
2 predetermined antigen in a sample of whole blood, comprising the steps of:

3 providing a sample of the whole blood;

4 adding a hemolysis reagent and a latex reagent, including insoluble latex carriers
5 onto which antibodies specifically reacting with the predetermined antigen in the sample of
6 whole blood have been immobilized, directly to the sample of the whole blood without any pre-
7 treatment of the whole blood;

8 hemolysing the whole blood sample with the hemolysis reagent to hemolyse the
9 blood corpuscles;

10 reacting the hemolysed whole blood sample in an agglutination reaction to form
11 an agglutination reaction product wherein a predetermined antigen in the hemolysed whole blood
12 sample specifically reacts with ~~an antibody~~ the antibodies immobilized onto ~~an~~ the insoluble
13 ~~carrier~~ latex carriers;

14 irradiating the agglutination reaction product in the hemolysed whole blood
15 sample with radiation which includes a wavelength within a range of 700 nm to 1000 nm which
16 is substantially free from absorption by both hemoglobin and the hemolysis reagent; and

Patent
42479-2500

17 measuring, only ~~in a~~ within the wavelength range which is free from absorption
18 ~~by both hemoglobin and the hemolysis reagent of 700 nm to 1000 nm~~, an absorbance of the
19 incident radiation with the agglutination reaction product to determine the quantity of antigens in
20 the sample.

1 14. (Currently Amended) The agglutination immunoassay method of Claim 13
2 further including the step of determining the CRP C-reactive protein (CRP) component in plasma
3 in the hemolysed whole blood sample.

1 15. (Currently Amended) The agglutination immunoassay method of Claim 13
2 wherein the wavelength ~~range~~ is approximately at 800 nm for measuring.

1 16-18. (Cancelled)

1 19. (Currently Amended) A particle agglutination immunoassay method of
2 quantifying a predetermined antigen in a sample of whole blood, comprising the steps of:
3 providing a sample of the whole blood;
4 adding a hemolysis reagent to the sample of whole blood;
5 hemolysing blood corpuscles in the sample of whole blood to enable a subsequent
6 immunoreaction;
7 adding a latex reagent, including insoluble latex carriers onto which antibodies
8 specifically reacting with the predetermined antigen in the sample of whole blood have been
9 immobilized, to the hemolysed whole blood;
10 providing an agglutination reaction with the hemolysed whole blood sample to
11 form an agglutination reaction product of particles wherein a predetermined antigen in the

Patent
42479-2500

12 hemolysed whole blood sample reacts with the antibodies immobilized on the insoluble carrier
13 particle to provide the agglutination reaction product;
14 irradiating the agglutination reaction product in the hemolysed whole blood
15 sample with radiation which includes a wavelength of approximately 800 nm which is
16 substantially ~~tree~~ free from absorption by both hemoglobin and the hemolysis reagent; and
17 measuring, only with the wavelength of approximately 800 nm, a change in
18 absorbance of the incident radiation by the agglutination reaction product to determine the
19 quantity of antigens in the sample.

1 20. (Previously Presented) The particle agglutination immunoassay method of Claim
2 19 wherein the hemolysing reagent is saponin.

1 21. (Currently Amended) The particle agglutination immunoassay method of Claim
2 19 wherein the ~~measuring also determines CRP of plasma components~~ predetermined antigen is
3 the C-reactive protein (CRP) composed in plasma in the hemolysed whole blood sample.

1 22. (Cancelled)

1 23. (Currently Amended) The immunoassay method of Claim 9 wherein the
2 wavelength ~~range is at~~ approximately 800 nm.

1 24. (New) The agglutination immunoassay method of Claim 13 wherein the
2 hemolysing reagent is saponin.